Consent Form

Title of Research Study: ***FMBI with War-Affected Families***

Investigator Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Sarah Hoffman
Investigator Departmental Affiliation: University of Minnesota School of Nursing
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Supported By: This research is supported by The University of Minnesota Clinical and Translational Science Institute.

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

Intergenerational trauma is when difficult experiences that mothers and fathers have had affect their children's wellbeing. This program has been developed to support families coming to the United States as refugees. We know the changes you experience can be challenging. We want to help you build skills as parents to work out those challenges. And, we want to provide your children with tools so they can continue to grow in healthy ways.

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What is research?

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because your family took part in earlier phases of the project with Dr. Hoffman and you reported trauma or difficult experiences in the past in the earlier phases of this research *(if potential participant participated in an earlier project phase) OR A WellShare community health worker or program coordinator referred you to the project (if identified by WellShare)*. Based on what we learned we developed this program. We are now asking several families to go through the program to find out what they think of the program and whether it is helpful.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

If you consent to your child's participation, youth will participate in a group delivery format. The format will be in person groups consisting of 5-10 group members. The location of the group will be the Knyaw Baptist Church. Masks will be required and social distancing will be promoted. Groups will only consist of youth taking part in the intervention. You will have the option of transporting your child, or transportation by the church van will be arranged as an alternative. Youth will be instructed that all content of the intervention sessions is to remain confidential. If youth do share personal information in the groups, there is no guarantee this information will stay within the group. They should only share what they are comfortable with fellow members knowing.

Why is this research being done?

We have started this program from other existing projects focused on families. The main difference is that we would like to deliver a program that helps refugee families that have come to the United States. We know that transition can be difficult for parents and children. Our goal is to help families develop tools and skills to work through family problems. We will look at the data collected to look at its effectiveness. Based on your feedback we will make small changes to the program so that it meets the needs of refugee families. Once we have done this, we will deliver the program to larger numbers of refugee families living in Minnesota.

How long will the research last?

We expect that you will be in this research study for 2 months. You will meet two times a week for about 1 hour in your home with a community health worker for a total of 7 weeks. We will ask you questions at the beginning and at the end of the program so we can learn more about how the program affected your parenting.

What will I need to do to participate?

You will be asked to talk with a community health worker during each 1 hour session about different aspects of parenting children. During the week, in between sessions, we will ask you to practice the skills that the community health worker teaches you. We are also asking you to give permission for your child to participate. A second community health worker will meet with them at the same time. Sometimes you will meet separately, sometimes the meetings will be together. The goal of the meetings with your child is to help them build skills to work through difficult experiences they have at home and at school.

*More detailed information about the study procedures can be found under **"What happens if I say yes, I want to be in this research?"***

Is there any way that being in this study could be bad for me?

Some of the questions we will ask you at the first visit are personal. As a result, you may have painful memories or feel upset. For most of the program we will be talking about experiences you are currently having with your child and about practicing healthy parenting skills. It is unlikely that this will be too upsetting or overwhelming, but if it is, the interviewer will stop immediately and provide you with professional assistance including a referral to mental health services or social services. If the program results in you needing walk-in counseling, we can refer you to the Wilder Foundation and/or the Ramsey County Urgent Care for Adult Mental Health to assist you in this matter. We would also use the same services to refer a caregiver who during an assessment indicates they are having a mental health concerns. These counseling services are offered on a sliding fee scale and either you or your insurance company will be responsible for the costs. No one will see the answers you provide other than the approved research staff.

The same is true for children. The program is positive and is not likely to cause any harm to your child. Rather, we will be teaching them skills to deal with difficult situations they will come across with friends, family, and at school. If in talking to your child we realize that there is a health concern, that

they are thinking too much of have heaviness in their hearts, we will notify you and help them get connected to the same resources we listed above.

*More detailed information about the risks of this study can be found under **"What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include that you will learn helpful ways to deal with stress and support your children and your family. As a result you may see improvements in your child's behavior as well as your family's ability to solve problems together.

What happens if I do not want to be in this research?

You can seek help with parenting and managing stress from mental health clinics, the study team can provide you with appropriate referrals.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about 36 people will be in this research study.

What happens if I say "*Yes, I want to be in this research*"?

If you agree to participate in the study, and you give us permission for your child to be in the study, the following what will take place:

During this visit will ask you and your family members demographic questions. We will ask questions about your health, how you deal with stress and your family. This visit will take 2 hours and will be private. We will not share your responses with your family members or anyone else. We will also ask your child similar questions about how they handle stress. When we finish the questions we will schedule the next session. If your child is invited to participate in the group format, the questions will be completed during the first session of the group.

Community Health Worker Home Visits (1 hour each visit, 2 times a week for 7 weeks)
They will meet with you and your child separately. Some sessions there will be time spent together. It is important if you agree to be in the study that we are able to schedule these times. During the last session, we will ask you the same kinds of questions we are asking today, to see what impacts the program had.

If you give us permission, we would like to tape record each session. This is because we are helping the community health workers learn how to deliver the program. It is not important what you say in

the tape. When we listen to the recording we will be focused on how they teach the program to you.

Later you will be invited to participate in an individual interview to talk about your experience in the program.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

Privacy and confidentiality risks: There is some risk of a data breach involving the information we have about you. We comply with the University's security standards to secure your information and minimize risks, but there is always a possibility of a data breach.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for: Meeting with the community health worker twice per week for 7 weeks along with other members of your family, and practicing the skills you learn at each session in the way the community health worker asks you to do.

What happens if I say "Yes", but I change my mind later?

If you take part in this research study, and want to leave, you should tell us. Your choice not to be in this study will not negatively affect your right to any present or future services through WellShare International, or your relationship with the University of Minnesota. The same is true if your child does not want to participate.

We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

If you stop being in the research, information about you that has already been collected may not be removed from the study database. We will ask your permission to use the information collected up to the point you ended your involvement in the study. We will also ask you why you are ending your involvement in the study.

Can I be removed from the research?

It's possible, though unlikely, that we will have to ask you to leave the study before you finish it. If this happens, we will tell you why.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Additional sharing of your information for mandatory reporting
If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

What will be done with my data when this study is over?

Your data will not be used for any future research after this study is complete.

Certificate of Confidentiality

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children or vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay each parent and child participant $10 in a form of a gift card for each study visit completed (16 visits total, 2 assessment visits and 14 home visits). The total each parent and child can receive is up to $160 for a total of $480 as a family. If your child participates in the group format they will have a total of six visits, for a total of $80 ($400 as a family).

You will be invited to participate in a post program individual interview or focus group, each parent and child participant that participates will receive a $10 gift card. WellShare will provide gift cards to you with the amount described.

Use of Identifiable Health Information

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099
Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes, I agree	No, I disagree	
_____	_____	The investigator may audio or video record me to aid with data analysis. The investigator will not share these recordings with anyone outside of the immediate study team.
_____	_____	The investigator may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the investigator will attempt to limit such identification. I understand the risks associated with such identification.
_____	_____	The investigator may contact me in the future to see whether I am interested in participating in other research studies by Sarah Hoffman.

SIGNATURES:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

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_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

WITNESS STATEMENT:
The participant was unable to read or sign this consent form because of the following reason:

☐ The participant is unable to read the information

☐ The participant is visually impaired

☐ The participant is non-English speaking

☐ The participant is physically unable to sign the consent form. Please describe:

_____

☐ Other *(please specify)*:

_____

For the Consent of Non-English Speaking Participants when an Interpreter is Used:
A**s** someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____ _____
Signature of Interpreter Date

_____
Printed Name of Interpreter

OR:

Statement from a Non-Interpreter:
As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____ _____
Signature of Individual Date

_____

Printed Name of Individual